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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,855	03/19/2008	Marc V. Gorenstein	524287-0353594(WAA-348-PC	2017
43840	7590	06/14/2010		
Waters Technologies Corporation			EXAMINER	
34 MAPLE STREET - LG			HARWARD, SOREN T	
MILFORD, MA 01757				
		ART UNIT	PAPER NUMBER	
		1631		
		MAIL DATE	DELIVERY MODE	
		06/14/2010	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/588,855

Applicant(s)

GORENSTEIN ET AL.

Examiner

Soren Harward

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 2,5-9,11,14-18,20 and 23-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,10,12,13,19,21 and 22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 20060809, 20080611.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 2, 11 and 20, drawn to a method and system of tracking entities in LC/MS by setting coarse retention time and mass thresholds.

Group II, claims 4, 13 and 22, drawn to a method and system of tracking entities in LC/MS by looking up entities in a retention-time map.

Group III, claims 5, 14 and 23, drawn to a method and system of tracking entities in LC/MS by setting fine retention time thresholds and mass values.

Group IV, claims 6, 7, 15, 16, 24 and 25, drawn to a method and system of tracking entities in LC/MS by matching entities on retention times and masses with filtered retention time maps.

Group V, claims 8, 9, 17, 18, 26 and 27, drawn to a method and system of tracking entities in LC/MS by filtering the entities.

2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The shared technical feature is that of matching entities between two injections based on retention times and mass values (e.g. claims 1, 10 and 19); however, this shared feature is not a *special* technical feature, because it is taught by the prior art. For an in-

depth explanation of how this feature is taught by the prior art, please see the rationale for the rejection under 35 USC § 103 given below.

3. During a telephone conversation with Jamie Rose on 3 Jun 2010 a provisional election was made without traverse to prosecute the invention of group II, claims 4, 13 and 22.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 2, 5–9, 11, 14–18, 20 and 23–27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

5. Applicant's claim under 35 U.S.C. 119 for the benefit of prior-filed Provisional Application No. 60/544501 is acknowledged.

Information Disclosure Statement

6. The information disclosure statements (IDSs) submitted on 9 Aug 2006 and 11 Jun 2008 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered in full by the examiner. A copy of each IDS, signed by the examiner, is being attached to this Office action.

Specification

7. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "System and Method for Tracking Chemical Entities in an LC/MS System".
8. The disclosure is objected to because it contains an embedded URL and/or other form of browser-executable code (0098). Applicant is required to delete the embedded URL and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112, Second Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
10. Claims 1, 3, 4, 10, 12, 13, 19, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
11. Claims 1, 10 and 19 recite the limitation "assigning reference retention times based on the retention time map", which does not specify to what the reference retention times are assigned. Are they assigned to peaks, to entities, to subsets of entities, to injections, or something else? Hereinafter, this limitation will be interpreted as though the reference retention times are assigned to entities.
12. Claims 10, 12 and 13 recite the limitations "means for choosing", "means for comparing", *inter alia*, thus invoking 35 U.S.C. 112, sixth paragraph. The instant specification is silent with respect to what structure constitutes an adequate "means", and
- if one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.

(*In re Donaldson Co.*, 16 F.3d 1189 at 1195, 29 USPQ2d 1845 at 1850 (Fed. Cir. 1994) (in banc)).

13. Claims 4, 13 and 22 recite the limitation "the look-up table", for which there is no antecedent basis. Hereinafter, this limitation will be interpreted to be equivalent to the retention time map.

Claim Rejections - 35 USC § 112, First Paragraph

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 10, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

16. As stated above, the "means for" limitation of this claim is interpreted as invoking 35 U.S.C. 112, sixth paragraph. However, the specification is silent with respect to what structure constitutes an adequate "means", and thus fails to provide a proper written description of the invention. Per MPEP 2181:

In the situation in which the written description only implicitly or inherently sets forth the structure, materials, or acts corresponding to a means- (or step-) plus-function ... the examiner should [] have the applicant clarify the record by amending the written description such that it expressly recites what structure, materials, or acts perform the function recited in the claim element.

Claim Rejections - 35 USC § 101

17. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

18. Claims 1, 3, 4, 10, 12 and 13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

19. Claims 1, 3 and 4 are directed to a method of tracking entities in an LC/MS system. As established by the U.S. Supreme Court (see *Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673 (U.S. 1972); *Diamond v. Diehr*, 450 U.S. 175, 209 USPQ 1 (U.S. 1981)), and in accord with the decision in *In re Bilski* (545 F.3d 943, 88 USPQ 2d 1385 (Fed. Cir. 2008)), a claim to a process or method must meet one of two requirements to be eligible under 35 U.S.C. 101 as statutory subject matter. Either the critical steps of the method must be tied to a particular machine or apparatus, or the method must transform a particular physical article into another state or thing. In other words, the prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept may have a practical application, a claim reciting an algorithm or abstract idea can state statutory subject matter if and only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. 101 (i.e., a machine, manufacture, or composition of matter).

20. The method does not perform a real-world transformation of any physical article; it transforms only data (i.e., mathematical abstractions) related to LC/MS. Even though the data are derived from physical matter, and the step of acquiring the data is implicit in the practice of the method, inclusion of data-gathering steps do not render a method statutory (*Bilski*, 545 F.3d 943 at 957, 88 USPQ 2d 1385 at 1397). The claims also recite a series of calculations and algorithmic steps, but do not tie the method steps that are critical to the practice of the invention to any particular machine or apparatus. Even though carrying out such calculations by hand

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would be laborious, the claim language does not preclude this possibility. The instant claims thus fail both parts of the eligibility test, and are therefore non-statutory.

21. Claims 10, 13 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims are directed to a "system", which comprises "means" for performing certain algorithmic operations. Said "system" and "means" are defined neither in the claims nor in the specification, and therefore encompass embodiments of the invention which are purely software. Software, per se, is not statutory subject matter (see MPEP 2106 and *In re Nuijten*, 500 F.3d 1346, 84 USPQ 2d 1495 at 1500 (Fed. Cir. 2007)).

Claim Rejections - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

23. Claims 1, 3, 4, 10, 12, 13, 19, 21 and 22 are rejected under 35 USC § 102(b) and 35 USC 102(e) as being anticipated by Higgs (US 5,885,841; cited by Applicant on IDS of 11 Jun 2008).

24. With respect to claim 1, Higgs teaches a method of comparing two samples of proteins (*i.e.*, "entities"), comprising the following:

- a. fractionating two protein digest samples (clm 37(a–d)), possibly by liquid chromatography (clms 42 and 43); samples of organic species in general are claimed in clms 52–55
 - b. matching peak pairs between the two sets of samples (clm 37h), which constitutes both the “comparing the entities” and “identifying entities” steps
 - c. identifying retention time intervals for the peaks (clm 44), which constitutes “constructing a retention time map”
 - d. aligning the retention times of the samples (clm 46), which constitutes “assigning reference retention times” to the peaks
 - e. outputting results of the peak matching (clm 37(i)), which constitutes “tracking entities”
25. With respect to claims 10 and 19, Higgs teaches an apparatus that implements this method (clms 14–22).
26. With respect to claims 3, 12 and 21, Higgs teaches arrangements of data along defined axes (Fig. 3); since an axis is inherently sorted, this constitutes sorting the matched data.
27. With respect to claims 4, 13 and 22, Higgs teaches aligning the retention times of the two samples (clm 45), which inherently requires (or results in) determining whether one entity has a corresponding entry in the retention time map of the other sample. The alignment to a standard further establishes a “defined value” for the retention time if two entities match, and Higgs teaches the optional use of dynamic time warping to align two samples (clm 47), which constitutes interpolating the retention time values if they don’t match.
28. Higgs thus anticipates the claimed inventions.

Conclusion

29. No claim is allowable.

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bylund, *et al.* (*J Chromatogr A* 2002) and Nielsen, *et al.* (*J Chromatogr A* 1998) teach how to align LC/MS chromatograms by warping.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Soren Harward whose telephone number is (571)270-1324. The examiner can normally be reached on Mon-Thu 9:00-18:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Soren Harward/
Examiner, Art Unit 1631

/Michael Borin/
Primary Examiner, Art Unit 1631